



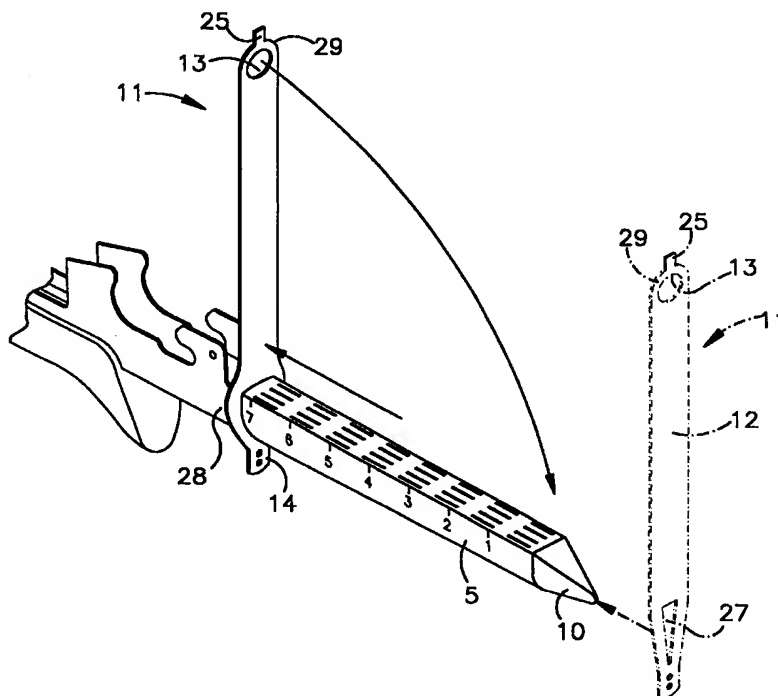
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(54) Title: PERICARDIAL STRIP AND STAPLER ASSEMBLY FOR DIVIDING AND SEALING VISCERAL TISSUES AND METHOD OF USE THEREOF

(57) Abstract

A pericardial strip (11) and surgical stapler (1) assembly, and method of use thereof, in which at least one pericardial strip (11) is releasably attached to the jaws (5, 6) of the stapler (1) by passing the outer ends of the stapler through holes (13, 27) in the strip(s) (11). Preferably, the trailing end(s) (14) of the strip(s) (11) are secured to the proximal ends of the jaws by O-ring(s) (23, 24), suture(s) attached to the trailing end of the strip(s) (11), or opening(s) (13, 27) in the strip(s) (11). When the tissue is cut, the O-ring(s) (23, 24), suture(s) (15), or opening(s) (13) are also cut, thus permitting removal of the stapler (1) and allowing at least a portion of the pericardial strips (11) to remain.



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**PERICARDIAL STRIP AND STAPLER ASSEMBLY FOR DIVIDING
AND SEALING VISCERAL TISSUES AND METHOD OF USE THEREOF**

This Application is a Continuation-in-Part of U.S. Patent Application 09/041,091, filed March 12, 1998.

5 The present invention is directed to the surgical incision of visceral tissues of warm blooded animals, especially resection of all or a portion of the human lung. Although the following description will focus on lung tissue, the invention is applicable to visceral
10 tissues of virtually all types.

Background of the Invention

It has been known to use stapling devices to seal visceral tissue upon resection thereof. However, stapling of the lungs often results in an air leak
15 which is detrimental to the health of the patient. This is especially true when the resection is used to accomplish "lung reduction". Since the lung reserves of such patients are very limited, even a small air leak can be extremely detrimental and even fatal.

20 In order to minimize the foregoing problem, pericardial tissue has been used in conjunction with a surgical stapler. Typically, the pericardial tissue is

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retained on the jaws by a cloth or plastic sleeve. However, this makes the procedure cumbersome and awkward. The foregoing is particularly true if the procedure is endoscopic.

5 The surgical stapler comprises three principal parts. One contains the staples, the other constitutes an anvil which receives the staples and initiates bending them in the proper direction, and the third, which is optional, is the knife which puts the final
10 bend on the staples and cuts the tissue where desired.

Surgical staplers usually are designed to insert two rows of staples, spaced apart from each other in a direction perpendicular to the longitudinal axis of their jaws. In such a case, the knife cuts between the
15 two rows.

Summary of the Invention

In order to solve the foregoing problem, the present invention eliminates the cloth or plastic sleeve. This is accomplished by using a pericardial
20 strip and surgical stapler assembly wherein the strips are provided with an opening adjacent their leading ends. The intermediate section extends from the leading end to the trailing end remote therefrom. The openings in the pericardial strips are placed over the
25 distal ends of the two jaws of the stapler. This retains the leading ends of the strips on the jaws. In addition, in a preferred form of the invention, the trailing ends of the strips are secured to the proximal ends of the jaws by an O-ring, also preferably made of
30 pericardial tissue. In an alternative form of the

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invention, the trailing ends of the strips are provided with sutures whereby the surgeon can manually tie them to the jaws.

In a second embodiment of the invention, the pericardial strip has a hole adjacent the trailing end. Thus, the distal end of the jaw of the stapler enters the hole and the trailing end is slid to a point adjacent the proximal end thereof. Then, the opening at the leading end is slipped over the distal end of the jaw, thereby securing the strip thereto at both ends. This eliminates the necessity for the O-ring.

Once the assembly has been inserted and the visceral tissue which is to be cut placed between the jaws, the stapler is actuated and it drives the - preferably double - row of staples through the two pericardial strips and the tissue against an anvil which initiates bending of the staples. Thereafter, the knife both cuts the tissue as desired and bends the staples further so that they are permanently attached. At the same time, this will sever the O-ring or the sutures so that the stapler may be readily removed and the pericardial strips left behind to seal the lung. In place of the O-ring, there can be provided suitable sutures which are applied manually by the surgeon. In those cases in which the stapler is not provided with a knife, it is removed after the staples have been driven and surgical scissors or another instrument is used to cut the tissue and the O-ring or sutures.

Brief Description of the Drawings

Preferred embodiments of the present invention are illustrated in accompanying drawings, with like characters indicating like parts, in which:

5 Fig. 1 is a plan view of the pericardial strip;

 Fig. 2 is a schematic view of one jaw of a surgical stapler;

 Fig. 3 is a schematic perspective view showing the pericardial strip fully attached in solid lines and
10 partially attached in broken lines;

 Fig. 4 is a perspective view of a typical surgical stapler as used in the present invention;

 Fig. 5 is a schematic partial view of the jaws of a surgical stapler with the pericardial strips
15 attached;

 Fig. 6 shows the surgical stapler being applied to visceral tissue;

 Fig. 7 is a view, similar to that of Fig. 6, wherein surgical scissors are cutting the visceral
20 tissue;

 Fig. 8 is a view, similar to that of Fig. 1, showing the sutures attached to the trailing end of the pericardial strip;

 Fig. 9 is a plan view of one form of O-ring;

25 Fig. 10 is a view, similar to that of Figure 9, of a second form of O-ring;

 Fig. 11 is a plan view of the second embodiment of the pericardial strip of the present invention;

30 Fig. 12 is similar to Fig. 2 and shows a modification of the pericardial strip;

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Fig. 13 is a perspective view, showing the insertion of the trailing end of the pericardial strip of Fig. 12;

5 Fig. 14 is a view, similar to that of Fig. 3, showing the pericardial strip on a jaw of the stapler;

Fig. 15 is a view showing the pericardial strips on the visceral tissue;

Fig. 16 is a view, similar to that of Fig. 11, of a third embodiment of the present invention;

10 Fig. 17 shows the pericardial strip of Fig. 16 inserted on one jaw of the stapler;

Fig. 18 is a view, similar to that of Fig. 17, with both ends of the pericardial strip of Fig. 16 on the stapler; and

15 Fig. 19 is a view, similar to that of Fig. 18, with the O-ring securing the pericardial strip to the stapler.

Description of Preferred Embodiments

20 Surgical stapler 1, as shown in Figures 2 and 4, comprises handle 2, first jaw 5, and second jaw 6. Handle 2 consists of stationary part 3 and movable part 4. The staples (not shown) are stored in first jaw 5 and anvil 7 is provided on second jaw 6 to receive the staples and initiate bending thereof.

25 Staple holes 9 are provided on first jaw 5 and distal end 10 is preferably pointed for ease of insertion.

Pericardial strip 11 consists of a leading end having opening 13 and intermediate portion 12 extending to trailing end 14. As shown in Figure 3, opening 13
30 is placed over end 10 so that the leading end of

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pericardial strip 11 is releasably secured to jaw 5. As shown in solid lines, pericardial strip 11 is secured to jaw 5.

The operation of the assembly is shown in Figures 5 to 7. Openings 13 of pericardial strips 11 have been placed over ends 10 of jaws 5 and 6 of the surgical stapler. The trailing ends are secured by O-rings 23 or 24, shown in Figures 9 and 10. Such rings would come in two sizes, one of which would preferably carry an indicium, such as tab 25, so that the surgeon can readily distinguish between the sizes.

Alternatively, sutures 15 (Figure 8) can be used in place of O-ring 23 or 24. Movable part 4 is rotated about pivot 8 (Figure 4) so that second jaw 6 is adjacent first jaw 5 with lung 17 therebetween. Actuator 26 causes the staples to be driven through pericardial strips 11 and lung 17. Surgical scissors 21 are used to cut lung 17 into excised portion 18 and retained portion 19. The former is removed by forceps 22.

The leading ends of pericardial strips 11 may be removed along with excised portion 18 or, at the option of the surgeon, left in place. Thus, the incision line is sealed so that no air leaks occur.

Referring now to Figure 8, a modification of pericardial strip 11 is shown. It carries the same opening 13 and flat intermediate section 12 as does the device of Figure 1. However, at trailing end 14, sutures 15 are attached. This makes it convenient for the surgeon to tie the trailing end to jaw 5 or 6 of

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stapler 1. When lung 17 is cut, sutures 15 are also cut, thereby allowing end 10 of surgical stapler 1 to be slipped out of opening 13 and removed.

The second embodiment of the invention is best illustrated in Figs. 11-14. Pericardial strip 11 is substantially the same as in the first embodiment at leading end 29. However, trailing end 14 is provided with hole 27, preferably of triangular shape. Hole 27 is inserted over distal end 10 of (for example) first jaw 5 and slid to proximal end 28 as shown in Fig. 13. Thereafter, opening 13 is placed over distal end 10 as shown in Fig. 14, thereby securing pericardial strip 11 to first jaw 5. The smaller holes located at trailing end 14 are provided to enable the surgeon to enlarge the hole 27, such as by cutting from the hole 27 to the appropriate smaller, adjacent hole. Accordingly, the strip 11 may be adapted to fit other size staplers. A corresponding strip is placed on the second jaw in substantially the same manner. This eliminates the need for the O-ring. As in the first embodiment, tab 25 may be provided on one end of pericardial strip 11 to permit the surgeon to easily distinguish between two sizes.

The third embodiment is shown in Figs. 16-19. Pericardial strip 11 is approximately twice the length of either first jaw 5 or second jaw 6. The strip 11 may be configured to fit 30mm, 45mm or 60mm staplers. Fold 30 is provided intermediate opening 13 and hole 27. Hole 27 is inserted over distal end 10 of second jaw 6 and opening 13 is inserted over distal end 10 of

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first jaw 5. O-ring 16 is then slid over first jaw 5 (see Figs. 18 and 19) to secure pericardial strip 11 on the stapler.

5 In this form of the invention, only one pericardial strip is required, making it easier for the surgeon to manipulate.

Although only three embodiments of the present invention have been expressly disclosed, it is, nonetheless, to be broadly construed, and not to be
10 limited except by the character of the claims appended hereto.

From the above description of the invention, those skilled in the art will perceive improvements, changes and modifications. Such improvements, changes and
15 modifications within the skill of the art are intended to be covered by the appended claims.

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Having described the invention, the following is claimed:

1. A pericardial strip and surgical stapler assembly to divide and seal visceral tissue, said pericardial strip comprising an opening adjacent its leading end and an intermediate section extending from said opening to its trailing end remote from said leading end;

said surgical stapler comprising an operating handle, a first jaw and a second jaw, mounted on said handle, and movable toward and away from each other between an open position and a closed position, a first distal end on said first jaw and a second distal end on said second jaw, said first distal end and said second distal end being remote from said handle, a first proximal end on said first jaw and a second proximal end on said second jaw, said first proximal end and said second proximal end being adjacent said handle;

one said pericardial strip on said first jaw with said first distal end projecting into its opening, thereby to releasably secure said leading end to said first distal end, another said pericardial strip on said second distal end with said second distal end projecting into said opening, thereby to releasably secure its leading end to said second distal end;

when said first jaw and said second jaw are in said open position, they are spaced apart from each other, when said first jaw and said second jaw are in

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said closed position, they are adjacent each other with said visceral tissue therebetween; and

said stapler adapted to drive said staples through said one pericardial strip, said visceral tissue, and said other pericardial strip.

2. The assembly of claim 1 wherein the leading end of said one pericardial strip is releasably secured to said first jaw adjacent said first distal end, or the leading end of said other pericardial strip is releasably secured to said second jaw adjacent said second distal end.

3. The assembly of claim 2 wherein said trailing end of each of said one pericardial strip and said other pericardial strip is releasably secured adjacent said first proximal end and said second proximal end, respectively.

4. The assembly of claim 2 wherein said trailing end is releasably secured by an O-ring.

5. The assembly of claim 2 wherein sutures are provided adjacent said trailing end of said one pericardial strip, whereby said trailing end is releasably secured to said first proximal end, said suture adapted to release after actuation of said stapler.

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6. The assembly of claim 1 wherein there is more than one pericardial strip on at least one of said first jaw and said second jaw.

7. A method of dividing and sealing visceral tissue using the assembly of claim 1 comprising:

placing of said opening of said one pericardial strip over said first distal end, placing said opening of said other pericardial strip over said second distal end, whereby said leading end of said one pericardial strip and said leading end of said other pericardial strip are releasably secured to said first jaw and said second jaw, respectively;

inserting said assembly into a body of a warm blooded animal with said tissue between said first jaw and said second jaw, actuating said stapler to drive said staples through said one pericardial strip, said visceral tissue, and said other pericardial strip;

distorting of said staples to permanently secure said one pericardial strip and said other pericardial strip to said visceral tissue; and

cutting said visceral tissue adjacent said staples, and withdrawing said assembly from said body.

8. The method of claim 7 wherein said one pericardial strip comprises a first plurality of strips, and the opening of each of said first plurality of strips being placed over said first distal end.

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9. The method of claim 8 wherein said other pericardial strip comprises a second plurality of strips, the opening of each of said second plurality of strips being placed over said second distal end.

10. The method of claim 7 wherein said visceral tissue is a lung.

11. The assembly of claim 1 wherein there is a hole adjacent said trailing end, said hole being adjacent said first proximal end or said second proximal end when said pericardial strip is on said first jaw or said second jaw, respectively.

12. The assembly of Claim 11 wherein said hole is a triangle having an apex.

13. The assembly of Claim 12 wherein said apex is directed toward said trailing end.

14. A pericardial strip and surgical stapler assembly to divide and seal visceral tissue, said pericardial strip comprising an opening adjacent its leading end, an intermediate section extending from said opening to its trailing end remote from said leading end, and a hole adjacent said trailing end;

said surgical stapler comprising an operating handle, a first jaw and a second jaw, mounted on said handle, and movable toward and away from each other between an open position and a closed position, a first

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distal end on said first jaw and a second distal end on said second jaw, said first distal end and said second distal end being remote from said handle, a first proximal end on said first jaw and a second proximal end on said second jaw, said first proximal end and said second proximal end being adjacent said handle;

said pericardial strip on said surgical stapler with said first distal end projecting into said opening and said second distal end projecting into said hole, a fold in said intermediate section adjacent said handle;

when said first jaw and said second jaw are in said open position, they are spaced apart from each other, when said first jaw and said second jaw are in said closed position, they are adjacent each other with said visceral tissue therebetween; and

said stapler adapted to drive said staples through said one pericardial strip, said visceral tissue, and said other pericardial strip.

15. The assembly of claim 14 wherein said fold is releasably secured adjacent said handle.

16. The assembly of claim 15 wherein said fold is releasably secured by an O-ring.

17. The assembly of Claim 16 wherein said O-ring is severed when said stapler is activated.

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18. A method of dividing and sealing visceral tissue using the assembly of claim 14 comprising:

placing said hole or said opening over said first distal end, placing another of said hole or said opening over said second distal end, and releasably securing said fold adjacent said handle;

inserting said assembly into a body of a warm blooded animal with said tissue between said first jaw and said second jaw, actuating said stapler to drive said staples through said one pericardial strip, said visceral tissue, and said other pericardial strip;

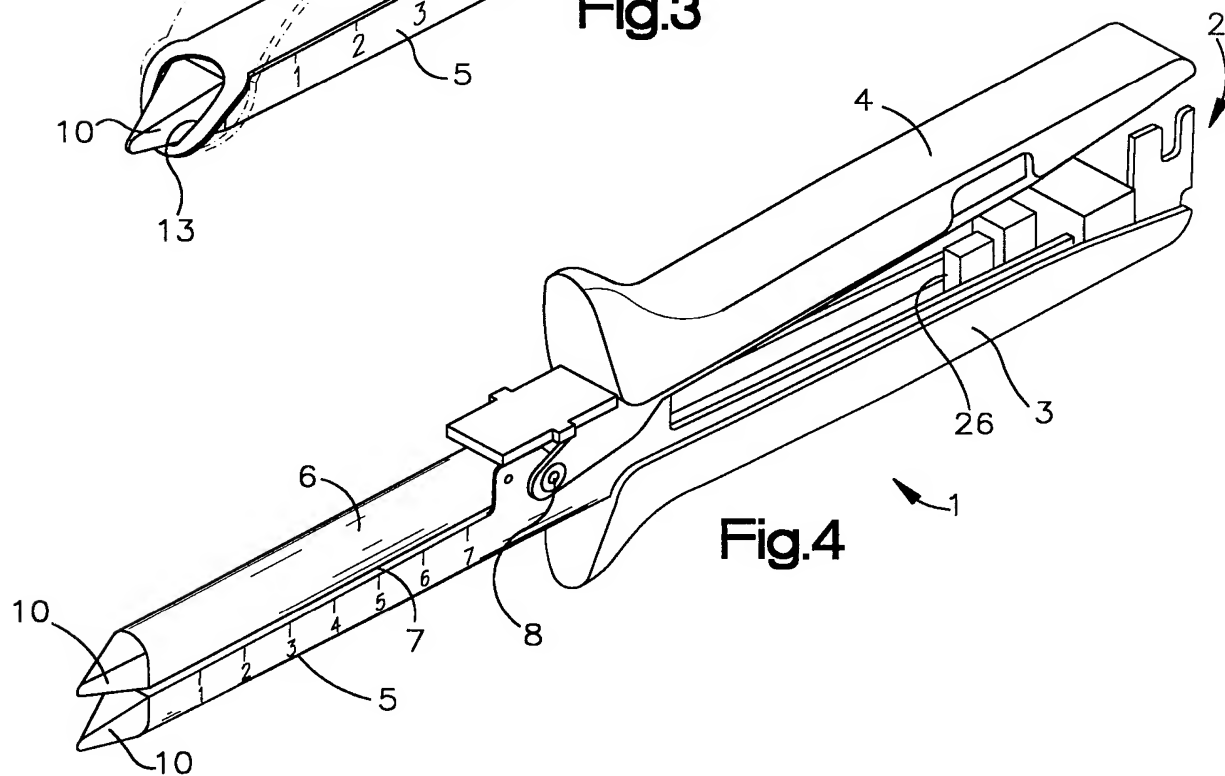
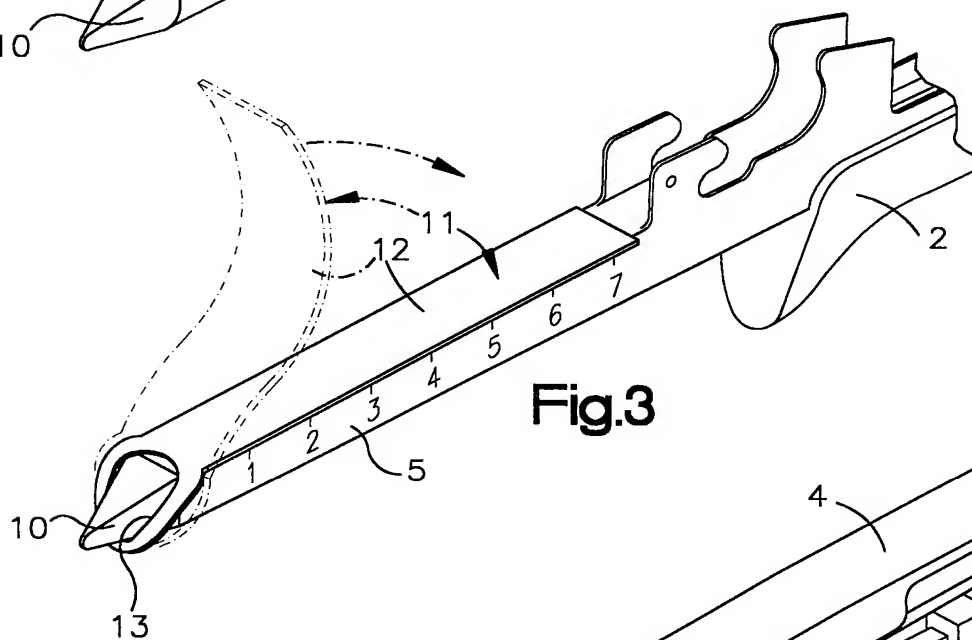
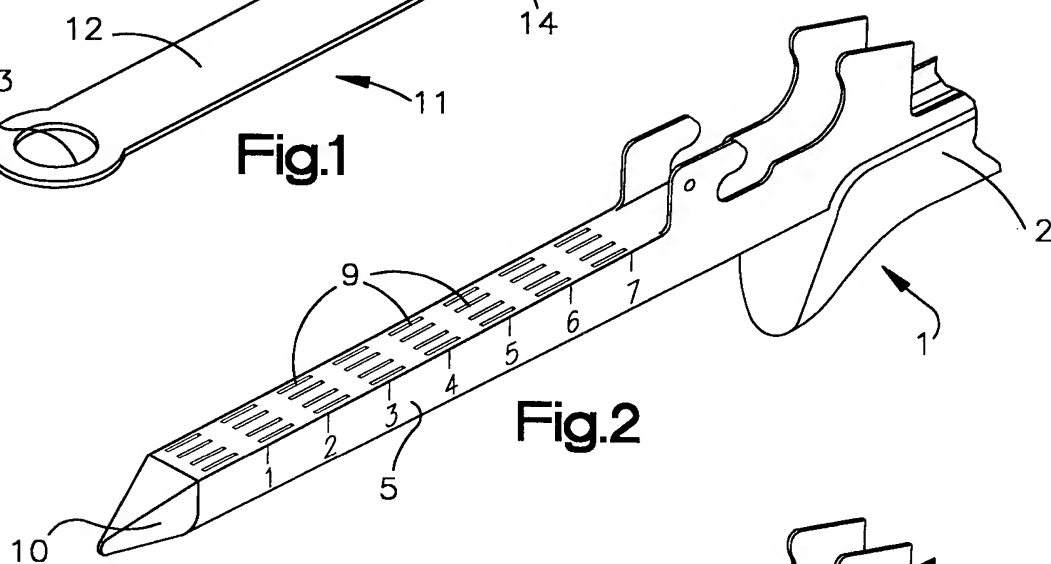
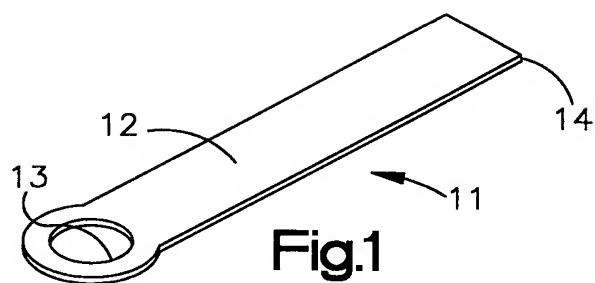
distorting said staples to permanently secure said pericardial strip to said visceral tissue; and

cutting said visceral tissue adjacent said staples, and withdrawing said assembly from said body.

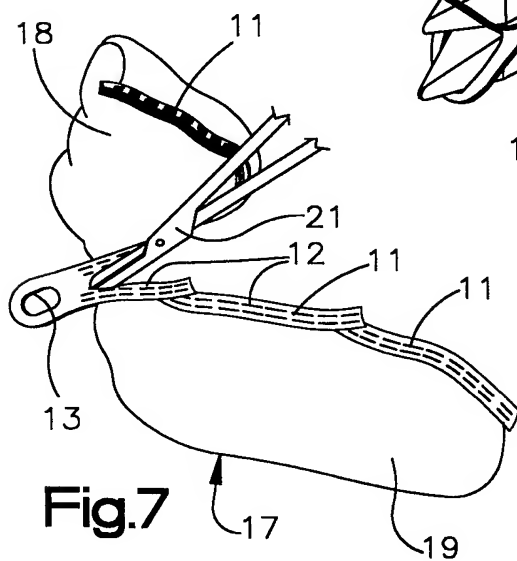
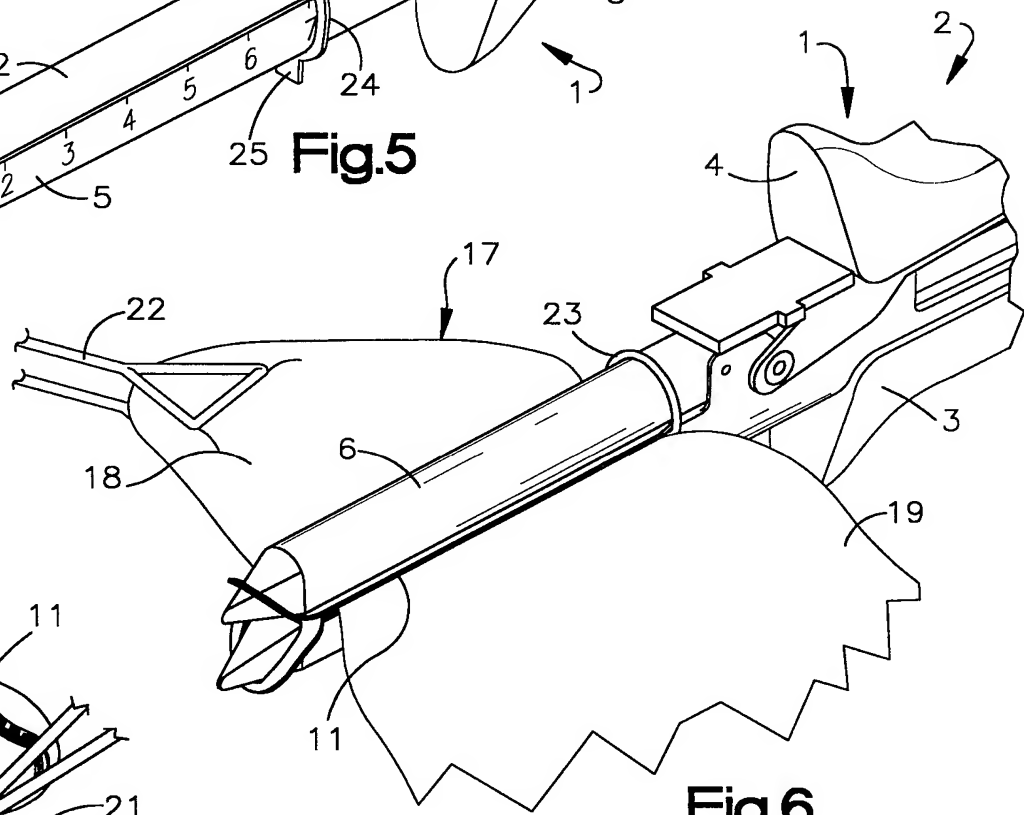
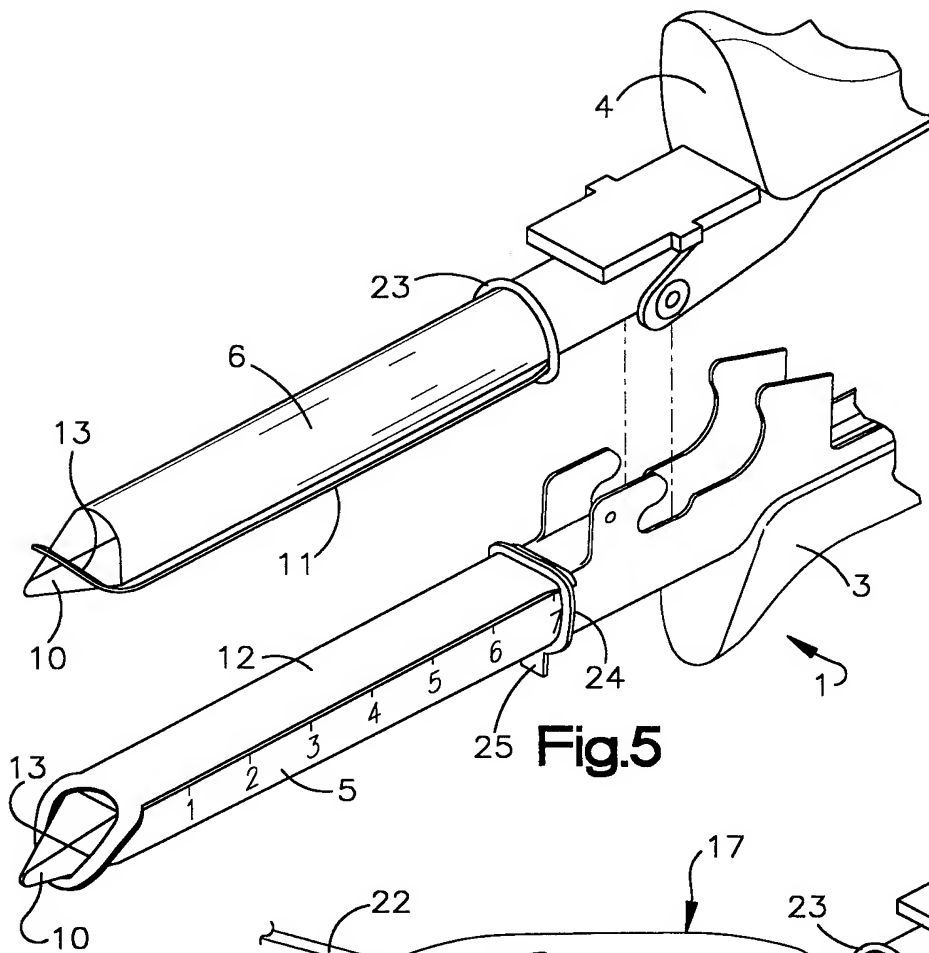
19. The method of claim 18 wherein an O-ring is slipped over said first jaw or said second jaw and slid adjacent said handle, thereby releasably securing said fold.

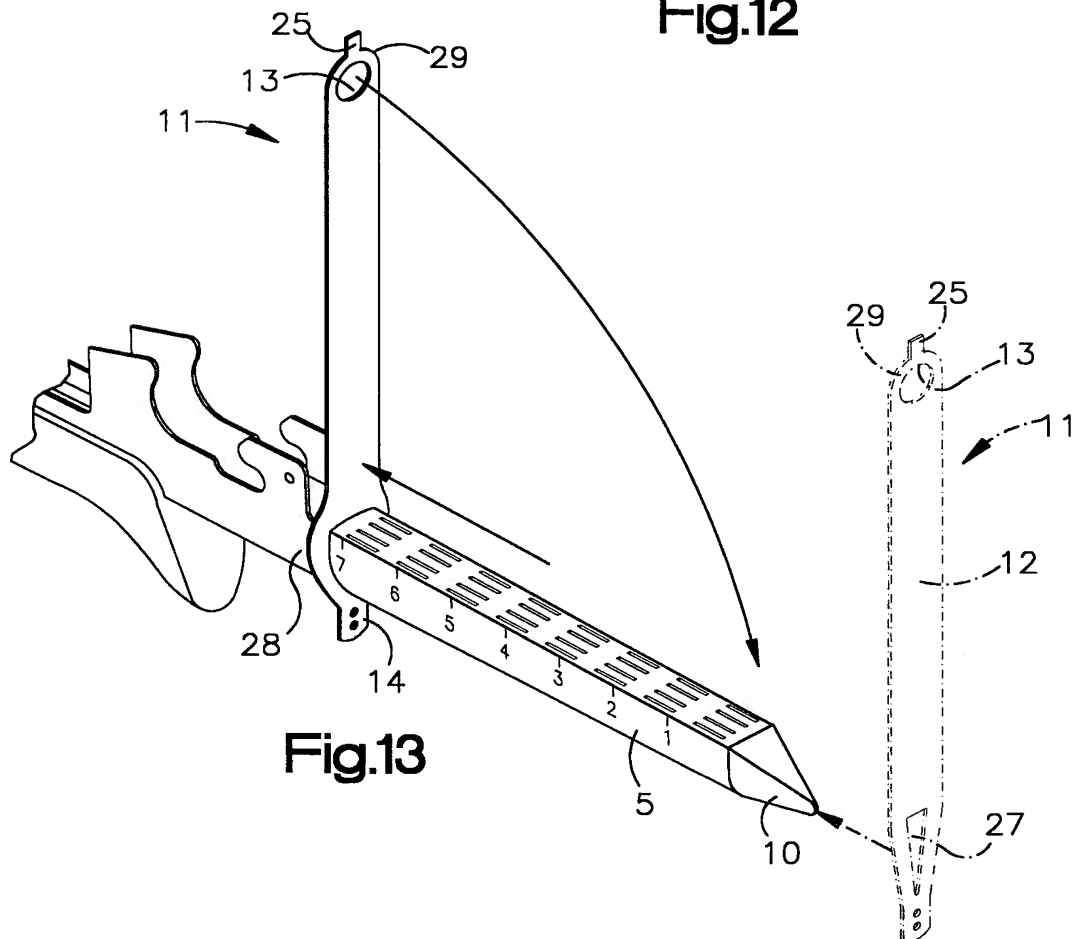
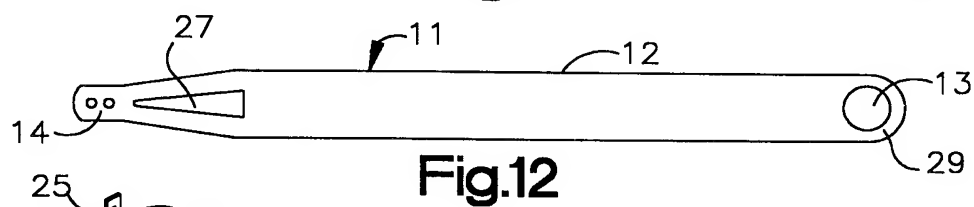
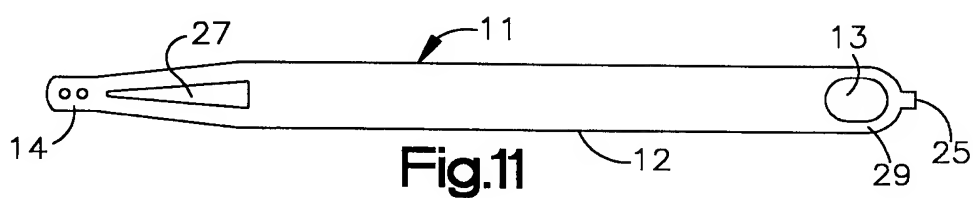
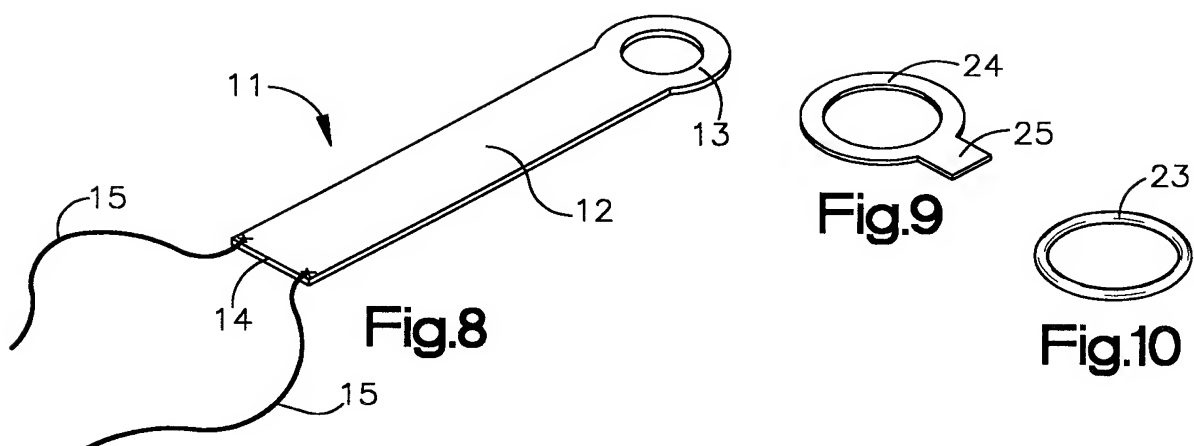
20. The method of claim 18 wherein there is a plurality of said pericardial strips, said method comprising placing each said hole or each said opening over said first distal end, and placing each other said hole or each other said opening over said second distal end.

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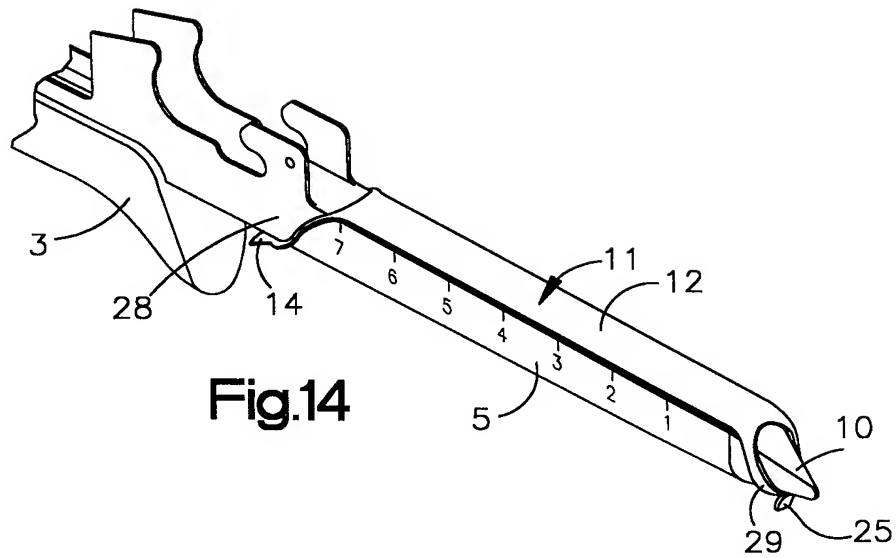


Fig.14

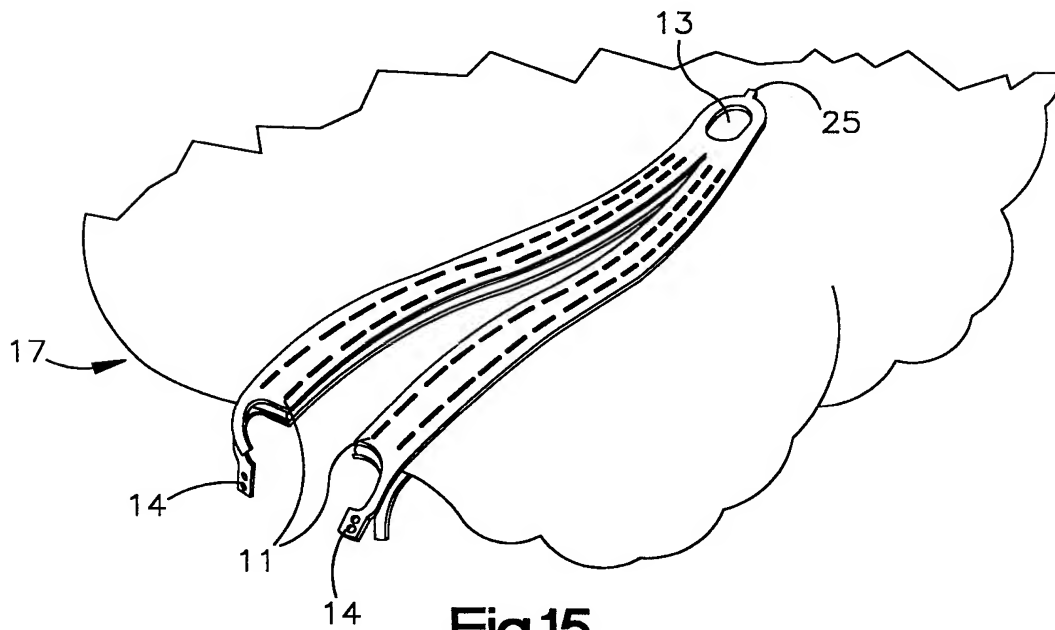


Fig.15

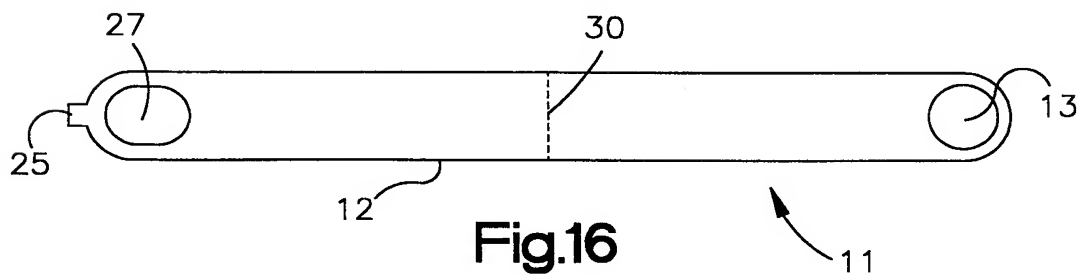
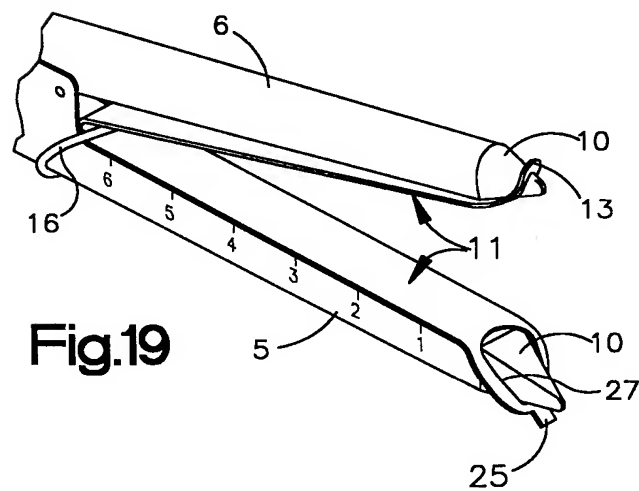
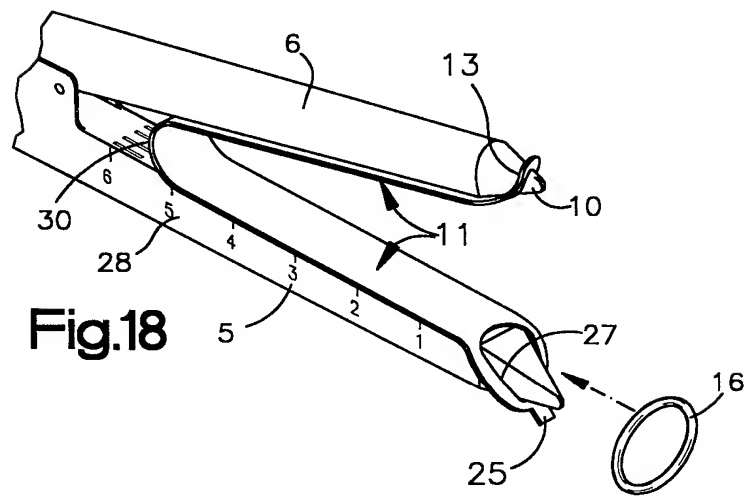
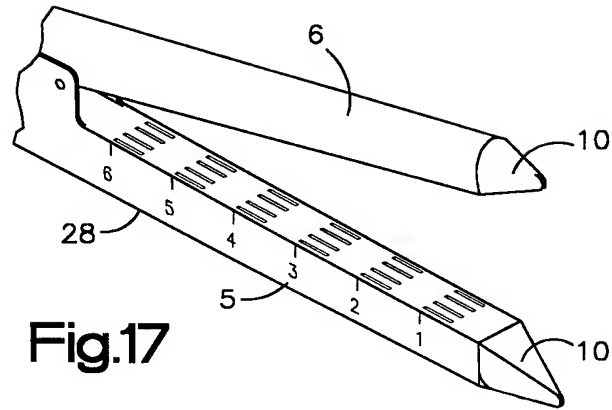


Fig.16

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/05308

A. CLASSIFICATION OF SUBJECT MATTER

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US CL : 606/139, 151

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/139, 151, 219

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,397,324 A (CARROLL et al.) 14 March 1995, entire document.	1-20

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